



4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0878]

Agency Information Collection Activities; Proposed Collection; Comment Request; Premarket Notification for a New Dietary Ingredient

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing an opportunity for public comment on our proposed collection of certain information. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice invites comments on the procedure by which a manufacturer or distributor of dietary supplements or of a new dietary ingredient is to submit information to us upon which it has based its conclusion that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers

Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

FDA PRA Staff, Office of Operations, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, we are publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invite comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Premarket Notification for a New Dietary Ingredient--21 CFR 190.6 (OMB Control Number 0910-0330)--Extension

Section 413(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 350b(a)) provides that at least 75 days before the introduction or delivery for introduction into interstate commerce of a dietary supplement that contains a new dietary ingredient, a manufacturer or distributor of dietary supplements or of a new dietary ingredient is to submit to us (as delegate for the Secretary of Health and Human Services) information upon which the manufacturer or distributor has based its conclusion that a dietary supplement containing a new dietary ingredient will reasonably be expected to be safe. Part 190 (21 CFR part 190) implements these statutory provisions. Section 190.6(a) requires each manufacturer or distributor of a dietary supplement containing a new dietary ingredient, or of a new dietary ingredient, to submit to the Office of Nutrition, Labeling, and Dietary Supplements (ONLDS) notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. Section 190.6(b) requires that the notification include the following: (1) The complete name and address of the manufacturer or distributor, (2) the name of the new dietary ingredient, (3) a description of the dietary supplements that contain the new dietary ingredient, and (4) the history of use or other evidence of safety establishing that the dietary ingredient will reasonably be expected to be safe.

The notification requirements described previously are designed to enable us to monitor the introduction into the food supply of new dietary ingredients and dietary supplements that contain new dietary ingredients, in order to protect consumers from the introduction of unsafe dietary supplements into interstate commerce. We use the information collected under these regulations to help ensure that a manufacturer or distributor of a dietary supplement containing a

new dietary ingredient is in full compliance with the FD&C Act. We are currently developing an electronic means for submitting this information.

Description of Respondents: The respondents to this collection of information are firms in the dietary supplement industry, including dietary supplement and dietary ingredient manufacturers, packagers and re-packagers, holders, labelers and re-labelers, distributors, warehouses, exporters, and importers.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in Hours) ²	Total Hours
190.6	55	1	55	20	1,100

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

We believe that there will be minimal burden on the industry to generate data to meet the requirements of the premarket notification program because we are requesting only that information that the manufacturer or distributor should already have developed to satisfy itself that a dietary supplement containing a new dietary ingredient is in full compliance with the FD&C Act. In the past, commenters argued that our burden estimate is too low. We revisited this issue and believe their burden estimate included the time it takes to research and generate safety data for a new dietary ingredient. However, sec. 190.6(a) requires each manufacturer or distributor of a dietary supplement containing a new dietary ingredient, or of a new dietary ingredient, to submit notification of the basis for their conclusion that said supplement or ingredient will reasonably be expected to be safe. Sec. 190.6 requests simply the extraction and summarization of the safety data that should have already been developed by the manufacturer or distributor. Thus, we estimate that extracting and summarizing the relevant information from the

company's files, and presenting it in a format that will meet the requirements of section 413 of the FD&C Act will require a burden of approximately 20 hours of work per submission.

We estimate that 55 respondents will submit one premarket notification each and that it will take a respondent 20 hours to prepare the notification, for a total of 1,100 hours. The estimated number of premarket notifications and hours per response is an average based on our experience with notifications received during the last 3 years and information from firms that have submitted recent premarket notifications.

Dated: August 20, 2013.

Leslie Kux,
Assistant Commissioner for Policy.

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